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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002952998 for a patent by COCHLEAR LIMITED as filed on 29 November 2002.

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J. Billingsley

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AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Cochlear electrode array assembly drug delivery device

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable device for use in delivering pharmaceuticals to a cochlea following implantation of a cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically includes the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal through a lead to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The electrode assembly is typically implanted through a cochleostomy formed in the cochlea and comprises an array of electrodes, with each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to an appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

There have been a number of proposals for delivering bio-active substances to the cochlea that are beneficial in promoting acceptance of the electrode assembly within the cochlea and/or assisting in the function of the

auditory nerve. One such proposal is described in the present applicant's International Application No PCT/AU01/01479 which describes use of a lumen within the electrode assembly that delivers bioactive substances directly within the cochlea following implantation of the assembly.

The present invention provides an alternative system for delivering beneficial bio-active substances to the region of the cochlea of a patient and particularly an implantee of a cochlear implant.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

Generally, the present invention provides a device that is adapted to assist in the delivery of pharmaceutical treatment to surrounding tissue following the insertion and positioning of an electrode assembly. Typically, the electrode assembly is positioned in order to apply electrical stimulation to a target region of tissue via dedicated electrical stimulating electrodes. The present invention is applicable to all types of tissue stimulating devices such as cochlear implants, deep brain implants, spinal cord implants and any other implantable devices that treat neurosensory or motorsensory loss or dysfunction.

It is a preferred feature of the present invention to provide a device that is adapted to assist the cochlea in its recovery from trauma following the

insertion of an electrode assembly therein. The present invention is equally applicable to conventional straight electrode assemblies and electrode assemblies which are designed to conform with the inner wall of the cochlea.

According to a first aspect, the present invention is a drug delivery device comprising:

a resiliently flexible elongate member having a proximal end and a distal end for implantation within a body;

wherein at least a portion of said elongate member is comprised of a biocompatible material, having at least one bio-active substance impregnated therein, said at least one bioactive substance being adapted to diffuse from the polymeric material following implantation of the member.

In this aspect, the resiliently flexible elongated member can form part of an implantable tissue-stimulating device having at least one electrode mounted thereon.

In another embodiment of this aspect, the drug delivery device can be separate to a tissue stimulating device but which acts in conjunction with said tissue stimulating device

According to a second aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation;

wherein at least one portion of said elongate member is comprised of a biocompatible polymeric material having at least one bio-active substance impregnated therein prior to implantation, said at least one bio-active substance being adapted to diffuse from the polymeric material following implantation of the member.

In a preferred embodiment of this invention, the device is a cochlear implant electrode assembly, with the elongate member adapted to be inserted through a cochleostomy formed in the cochlea and positioned therein.

In another embodiment, said portion of the biocompatible polymeric material is fully or partially encapsulated inside the material comprising the elongate member. In another embodiment, it can comprise a coating or be relatively near the surface of the elongate member. In one embodiment, the portion extends into the elongate member from at or adjacent the distal end. In this and other embodiments, the portion can extend for a majority of the length of the elongate member. In another embodiment, the portions extends the entire length of the elongate member between the proximal end and the distal end thereof. In this embodiment, said portion can be of constant diameter along its length. In another embodiment, said portion can vary in diameter along its length. For example, the diameter of said portion can decrease from the proximal end towards the distal end of the elongate member.

In a still further embodiment, one or more openings can be provided in the elongate member to allow bioactive substances in said portion to diffuse from said portion and exit the elongate member. An opening can be provided at the proximal end and/or the distal end of the elongate member. In another embodiment, there can be one or more openings between the proximal end and the distal end. Where there is more than opening, the openings can be regularly or irregularly spaced along the elongate member.

In a still further embodiment, said at least one portion can be disposed in the outer face of the elongate member. In one embodiment, said portion can comprise a ring member disposed in the outer face of the elongate member. In another embodiment, said portion can comprise a portion of a ring member, such as a half-ring. In another embodiment, a number of portions can be disposed along the locus of a ring formed in the outer surface of the elongate member. In a still further embodiment, there can be provided a plurality of rings or ring portions, such as half rings, in the outer surface of the elongate member. In these embodiments, the one or more portions can be at least substantially flush with the outer surface of the elongate member. In another embodiment, the one or more portions can stand proud of or be recessed in the elongate member.

In a still further embodiment, the portions can be disposed adjacent said one or more electrodes in the elongate member. In another embodiment, at

least one of said portions can be disposed between each of the electrodes mounted on the elongate member.

In a still further embodiment, one of said portions can be disposed around one, each of some or each of all the electrodes mounted in the elongate member. Where the electrode comprises a ring or ring portion, the portion can comprise an annular or part-annular member that surrounds the electrode.

In yet a further embodiment, the electrode can be disposed around a portion of said biocompatible polymeric material. Where a plurality of electrodes are mounted on the elongate member, some or each of the electrodes can be disposed around separate portions of said biocompatible polymeric material.

In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation. The bioactive substance can be an antibiotic, used for the reduction of bleeding, and/or a neural growth factor.

In a further embodiment, the elongate member of the stimulating device has a plurality of electrodes mounted thereon. The member can have a diameter of about 0.6mm. The member can also have a first configuration selected to allow said member to be inserted into an implantee's body, such as the cochlea, and a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes. In a further embodiment, the elongate member can have at least one intermediate configuration between said first and second configurations.

In a still further embodiment, at least a portion of the outer surface of the elongate member can have a coating of lubricious material. In a further embodiment, a substantial portion of the outer surface can have a coating of the lubricious material. In a still further embodiment, the entire outer surface of the elongate member can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used. It is envisaged that the lubricious material can also be impregnated with the bio-active substance allowing the coating to perform a dual role. The rate of delivery of the bio-active substance can be programmed by design of the coating structure.

In yet another embodiment, the device can include a stiffening element made of a second material relatively stiffer than the resiliently flexible material of the elongate member. The stiffening element can be adapted to bias the elongate member into the first configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration. In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

In one embodiment, the stiffening element can comprise a metallic stylet, or a stylet-like element formed from any other suitable stiffening material, extending through a lumen in the elongate member. In one embodiment, the wire can be formed from a biocompatible metal, a biocompatible metallic alloy

or a biocompatible relatively stiff plastic. In a preferred embodiment, a metal stylet can be formed from platinum.

The present invention provides a surgeon with an implantable component of a cochlear implant electrode array that can assist with the delivery of one or more bio-active substances to a position external the site of the cochleostomy during and/or following implantation of the component. The substances that can be delivered by the present device include substances that are adapted to promote healing, substances that prevent bleeding or at least excessive bleeding, and also substances that prevent the growth of tissue, including scar tissue, in the cochlea following implantation. Pharmaceutical compounds such as anti-inflammatories, neural growth factors and antibiotics can also be delivered by the present device.

It is also envisaged that substances that assist in reducing the resting potential of the surrounding neurons can also be delivered by the present invention. It should be appreciated that during neural stimulation the neurons propagate an action potential through the response of transmembrane ion channels to local electrical fields. By delivering a substance that elicits a change in the transmembrane potential, the resting neural membrane potential can be moved towards the activation potential resulting in a lowering of the energy required to be delivered to activate the neuron. This also has the potential to reduce the power required by the stimulation device as well as increase the specificity of the electrical stimulation and restore the stochastic response of the neurons.

The device can be adapted to only provide delivery of a bio-active substance to the preferred site for a particular period following implantation. This period may comprise any period of time from a few hours or days to a few weeks or even months. In another embodiment, the device can be used as a means of delivery of bio-active substances to the implantee well beyond the time of implantation. For example, the additional reservoir can be periodically filled with a bio-active substance to ensure continued supply of the bio-active substance to the implantation site. The additional reservoir, in this case, may be positioned beneath but adjacent the surface of the skin of the implantee

thereby allowing the reservoir to be filled by a syringe and needle assembly that injects the bio-active substance into the additional reservoir.

Once implanted, the electrodes can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of the electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator means. In this case, the body of the substance delivery means is preferably positioned around the lead prior to attachment of the lead to the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the

receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

According to a further aspect, the present invention is a method of delivering at least one bioactive substance to a desired site of action within a cochlea using a device as defined herein, the method comprising the steps of:

forming a cochleostomy;

inserting the elongate member through the cochleostomy;

allowing the bioactive substance to diffuse from the elongate member into the cochlea.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Fig. 2 is a simplified enlarged view of one embodiment of a prior art electrode assembly;

Fig. 2a is a cross-sectional view of the device of Fig. 2;

Fig. 3 is a simplified view of an electrode assembly according to the present invention;

Figs. 3a-3c are cross-sectional views of another embodiment of an electrode assembly according to the present invention;

Fig. 4 is a simplified view of another embodiment of an electrode assembly according to the present invention;

Fig. 5 is a simplified view of a still further embodiment of an electrode assembly according to the present invention;

Fig. 6 is a simplified view of a still further embodiment of an electrode assembly according to the present invention;

Fig. 7 is a simplified view of a still further embodiment of an electrode assembly according to the present invention;

Figs. 7a-7c are cross-sectional views of an electrode assembly according to the present invention;

Fig. 8 is a simplified view of a still further embodiment of an electrode assembly according to the present invention; and

Fig. 9 is a simplified view of a still further embodiment of an electrode assembly according to the present invention.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Figs. 1, 2a and 2b.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A lead 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20 that is passed through a cochleostomy and into the cochlea 12. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930, the contents of which are incorporated herein by reference.

As depicted more clearly in Figs. 2a and 2b, the array 20 typically comprises an elongate electrode carrier member 31 having a plurality of electrodes 32 mounted thereon. For the purposes of clarity, the electrodes 32 depicted in Fig. 2a and 2b are not necessarily shown to scale. A larger number of electrodes than that depicted in Fig. 2a can also be envisaged.

The depicted elongate member 31 is preformed from a resiliently flexible silicone with memory and can be preformed to a curved configuration suitable for insertion in the scala tympani of a human cochlea 12. While an assembly that normally adopts a curved configuration when in a relaxed condition is typically preferred, it will be appreciated that the present invention also could be

utilised with respect to assemblies that are normally straight when in a relaxed condition.

As depicted in Fig. 2b, the array 20 typically has a lumen 34 that, prior to insertion of the assembly 20 into the cochlea 12, can receive a substantially straight platinum stylet. Such a stylet typically has a stiffness that is sufficient to retain the silicone elongate member 31 in a straight configuration.

The depicted electrode assembly 20 has an electrical lead 21 extending back to a receiver/stimulator unit 22. In considering this invention, it is to be understood that each electrode 32 may have one or more wires 35 electrically connected thereto and extending from each respective electrode 32 back through the lead 21 to the receiver/stimulator unit 22.

A resiliently flexible elongate member according to the present invention is depicted generally as 40 in Figs. 3 and 3a. The member 40 has a plurality of electrodes 32 mounted thereon for delivering electrical stimulation to the cochlea 12.

Within the member 40 is at least a partially encapsulated member 41 of biocompatible material that has been impregnated with at least one bioactive substance. In this embodiment depicted in Fig. 3, the member extends for at least a majority of the length of the elongate member and is of a substantially constant diameter along its length.

As can be determined from a comparison of Figs. 3a and 3b, the cross-sectional shape of the member 41 can vary from one array to the next. Also, in another embodiment as depicted in Fig. 3c, the member 42 can be inserted through the lumen 34 used by the stylet during implantation of the array in the cochlea of an implantee.

As depicted in Figs. 4 and 5, the member 41 can vary in diameter along its length. For example, as depicted in Fig. 4, the diameter of the member 41 can gradually taper from the proximal end towards the distal end of the elongate member 40. In Fig. 5, the diameter decreases in a step-wise fashion from the proximal end towards the distal end.

Fig. 6 depicts a still further embodiment where an impregnated plug-like member 42 extends into the elongate member 40 from the distal end thereof.

One or more openings can be provided in the elongate member 40 to allow bioactive substances in the member 41 or 42 to diffuse from the member and exit the elongate member. Openings can be provided at various locations along the member, including the distal end 43 of the elongate member. Arrows A depict possible locations of diffused bioactive substance into the cochlea 12.

There can instead or also be one or more openings at a location spaced from the distal end 43. Where there is more than opening, the openings can be regularly or irregularly spaced along the elongate member.

As is depicted in Figs. 7-9, the elongate member can have impregnated members disposed in the outer face of the elongate member.

As depicted in Figs 7-7c, the impregnated members can comprise a ring member 60 (Fig. 7a) or a half-ring member 61 (Fig. 7b) disposed in the outer face of the elongate member. In another embodiment, the impregnated member can comprise a number of portions 62 that are disposed along the locus of a ring formed in the outer surface of the elongate member (see Fig. 7c).

Fig. 7 depicts how a plurality of rings 60 can be disposed between the electrodes 32 of the array. It will be appreciated that the rings 60 of Fig. 7 could be replaced in one, some, or all instances, by half-rings 61 or ring portions 62. In the depicted embodiment, the ring members 60 stand just proud of the outer surface of the elongate member. It will be appreciated that one or more of the ring members etc could be at least substantially flush with the outer surface of the elongate member or be recessed in the elongate member.

As depicted in Fig. 8, impregnated portions 70 can be disposed around the electrodes 32 mounted in the elongate member. Where the electrode

comprises a ring or ring portion, the portion can comprise an annular or part-annular member that surrounds the electrode 32.

As depicted in Fig. 9, the electrode 32 can be disposed around an impregnated portion 80 of biocompatible polymeric material.

In one embodiment, the bioactive substance can comprise a steroid. In another embodiment, the bioactive substance can perform a function of reducing the resting neuron potential of neurons within the cochlea. The use of such substances can result in less energy being required to excite the neurons and cause stimulation.

The provision of a system for delivering a pharmaceutical substance in the cochlea that promotes healing and/or more efficient neural stimulation while preventing the formation of substantial scar tissue in the cochlea, enhances the likelihood of successful long-term placement of the elongate member 40 in the cochlea and subsequent successful use of the cochlear implant by the implantee.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty ninth day of November 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

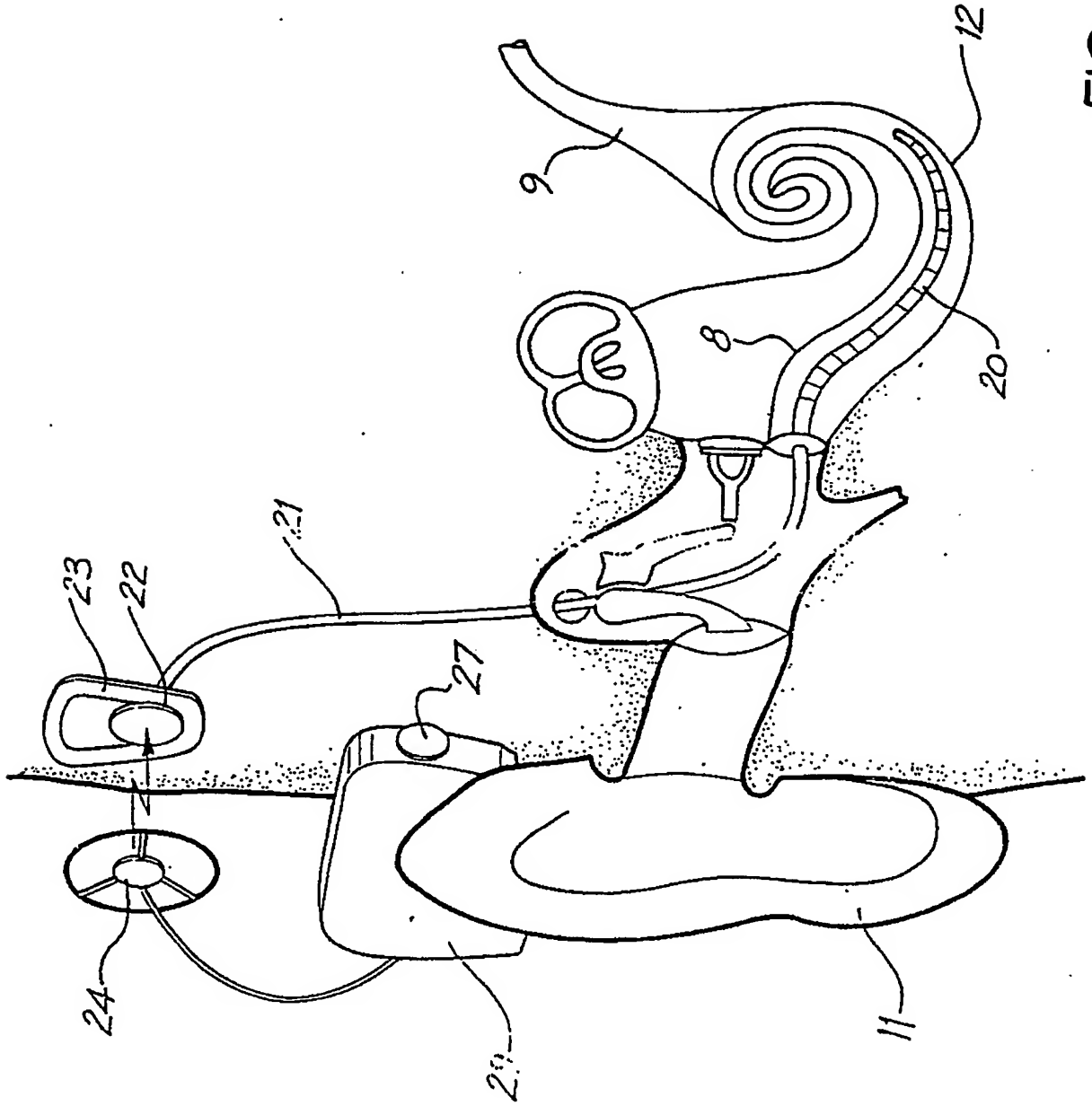


FIG. 1

Fig. 2a

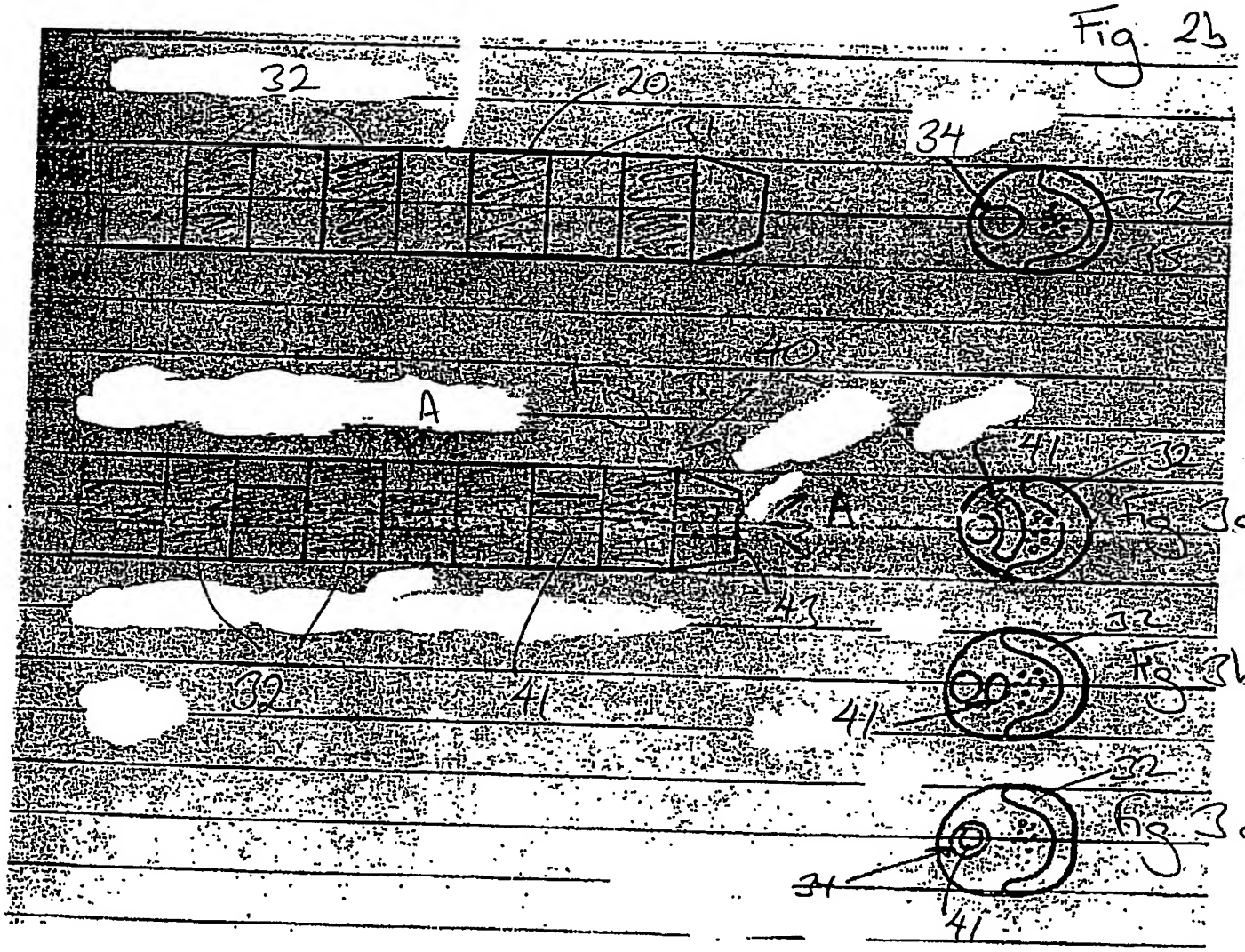


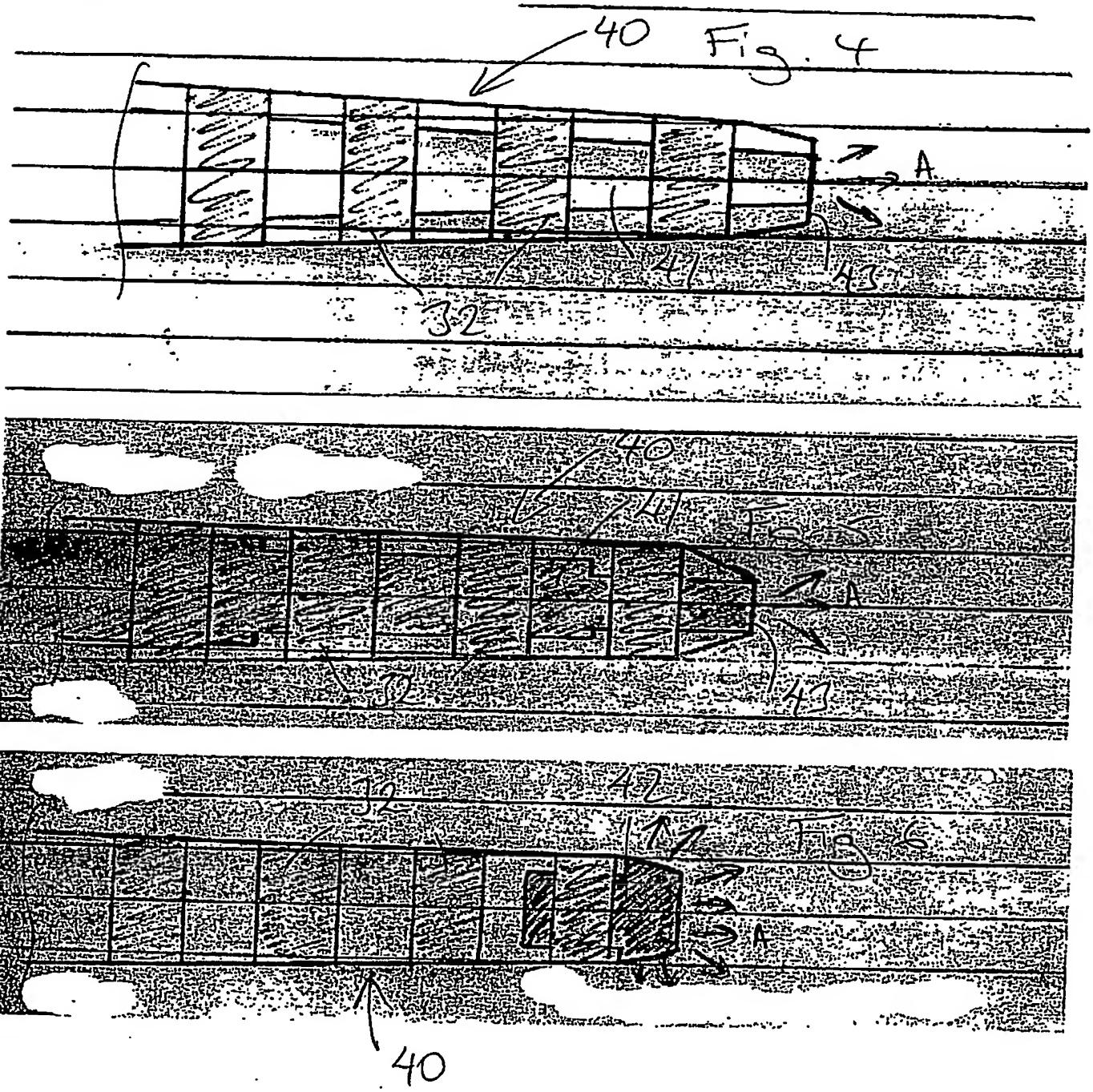
Fig. 2b

Fig. 3a

Fig. 3b

Fig. 3c

Fig. 4



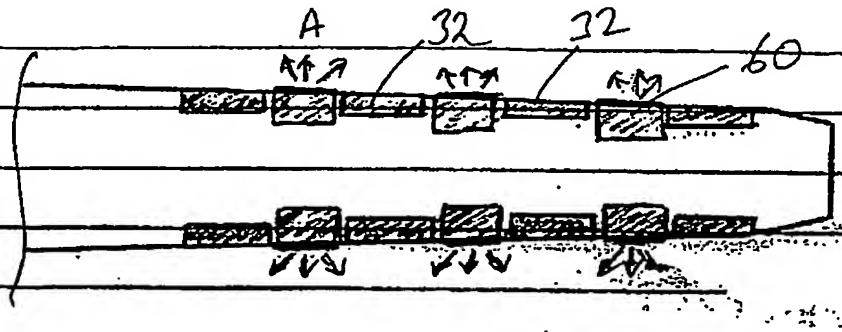


Fig. 7

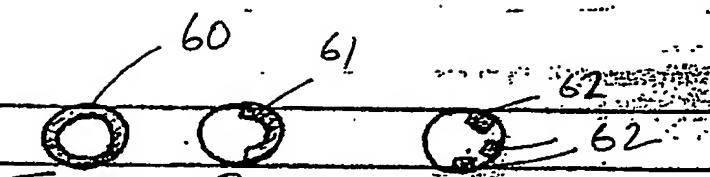


Fig. 7a Fig. 7b Fig. 7c

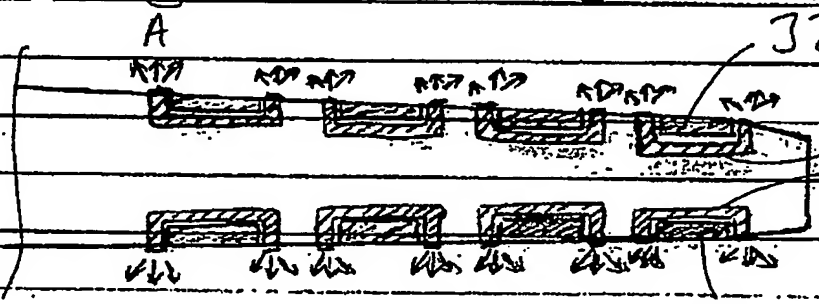


Fig. 8

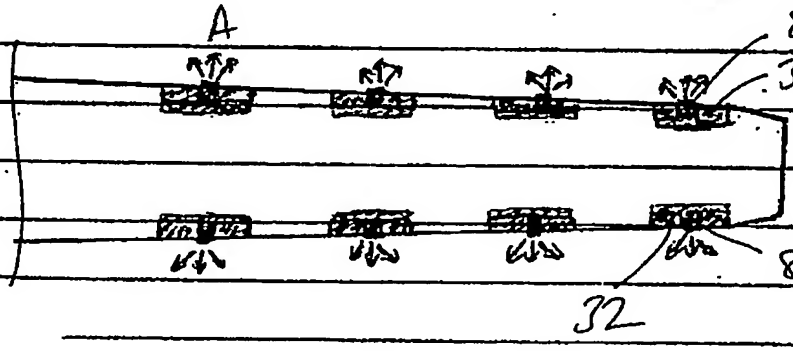


Fig. 9